



# International Filter Products

*Revolutionary systems for your industry*

## PureFlo® JKP Series PES 0.65 µm/0.2 µm – Dual Layer Filter Capsule

JKP Capsule filter assemblies are ready-to-use filters that offer high flows, increased throughputs, high strength, all with the convenience and cleanliness of a disposable and easy-to-install filter assembly in a small package. These capsules are designed for small pre-filtration, clarification, and final filtration, in pharmaceutical, and biotechnological applications. The filtration shell is an all-polypropylene construction that provides excellent chemical compatibility, truly flexible, clean, and optimal. The filters are manufactured in accordance with GMP and comply with <USP 797> guidelines. The filters are flushed with pharmaceutical-grade purified pyrogens-free water, and 100% integrity tested prior to dispatch. Our filters and free from animal-derived components raw materials can be traced by Lot Number and strictly regulated maintaining ISO 13485 & ISO 14001 quality standards.

### PureFlo® JKP - Series Filter Capsules



### 2H2H Connections

**Inlet:**

1/4" Hose Barb

**Outlet:**

1/4" Hose Barb



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## Application

- Buffers and Media
- SVP (Small Volume Parenteral)
- Vaccines
- Scale up processing
- Product Sterilization
- Bio Bags Compatible
- Biologics
- Ultrapure Water
- Fermentation Broths
- Pharmaceuticals
- Antibiotics
- Serums

## Technical Data Sheet

### Micron Rating:

**Final Membrane:** 0.2  $\mu\text{m}$  PES [Sterilizing Grade Membrane]

**Pre-Filter:** Highly Asymmetric 0.65  $\mu\text{m}$  PES

### Effective Filtration Area:

Junior Capsule; 40.3  $\text{in}^2$  (260  $\text{cm}^2$ )

### Materials of Construction:

**Membrane:** Pharmaceutical Grade PES (Polyethersulfone) Sterilizing Grade

**Membrane Feature:** Hydrophilic, Low Protein Binding, High Flow Rate

**Shell, Cage, Core, End Caps:** Polypropylene

**Valve O-Rings:** Silicone (Standard)

**Sealing:** Thermally Bonded

### Operating Conditions:

**Maximum Forward Differential Pressure:** **Liquid:** 5.5 bar (80psi) at 77°F/25°C

**Gas:** 4.1 bar (60psi) at 77°F/25°C

**Minimum Burst Pressure:** 8.3 bar (120psi) at 77°F/25°C

**Maximum Reverse Differential Pressure:** 3.0 bar (44psi) at 68°F/20°C

**Maximum Operating Temperature:** 176°F/80°C



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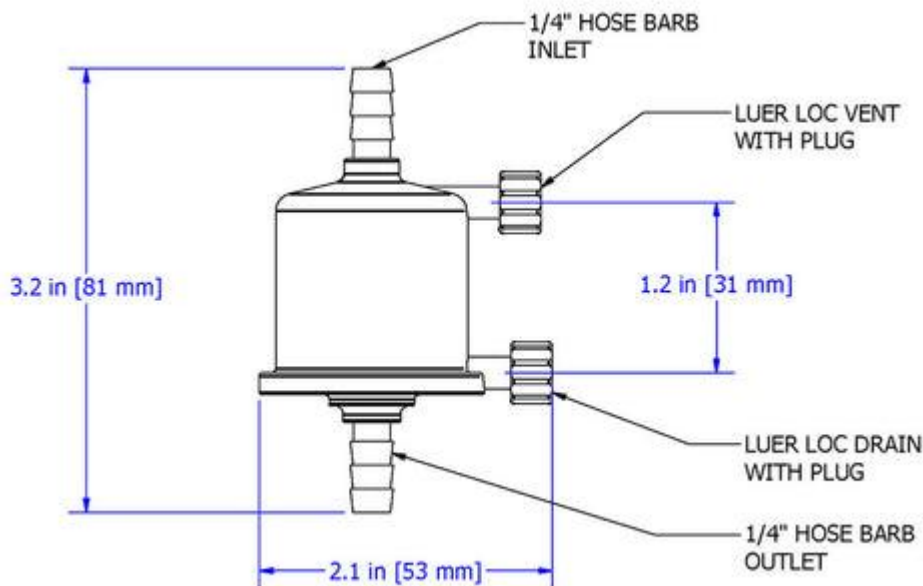
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## Nominal Dimension:



**2H2H  
Connections**

## Typical Filtered Volume:

**3.36L - 14.5L**

**[ Aqueous and alcohol base solutions ]**

\*Volume Filtered is an estimated range for Sterile Compounding, Pharmaceutical & Biological applications. The Filtration Volume is significantly influenced by your solution's viscosity, active ingredients, etc., properties. The best way to determine the exact filtration volume per filter is to try it with your solution.

## Hold-Up Volume (Approx.):

Upstream Volume: 7.7 ml

Downstream Volume: 0.9 ml

## Filter Integrity:

The finished product was sampled and shown to exhibit a minimum bubble point of  $\geq 18$  psi (1.2 bar) in 60%IPA / 40% water and  $\geq 50$  psi (3.5 bar) in DI Water (at 22°C ).



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## Bacterial Retention ASTM F838-05:

The filters are quantitatively retentive towards *Brevundimonas diminuta* (ATCC #19146) at a minimum challenge level of  $10^7$  CFU per  $cm^2$  of filtration area, consistent with ASTM F838-05

## Sterilization:

International Filter Products Inc. mostly stocks ETO Sterilized (Factory Sterilized) Filter Capsules.

Ethylene Oxide (ETO) Sterilization Process complies with ISO 10993-7:2008 Biological Evaluation of Medical Devices - Part 7. Each filter is subjected to a validated ETO process. Sterilization of the fluid path has been validated per ANSI/AAMI/ISO 11135 which provides a minimum sterility assurance level (SAL) of  $10^{-6}$ .

**Warning:** The filters cannot be sterilized by steam-in-place (SIP)

## Regulatory Compliance 21CFR Part 177 & USP <88>:

The filters are constructed with polypropylene resins and filtration media in compliance with 21CFR Part 177 of the US Code of Federal Regulations and USP Class VI Biological USP <88>Test for Plastic.

## USP <85> Bacterial Endotoxins:

The filters were tested to confirm that an aqueous extraction of this product contains <0.25 EU/ml as determined by the Limulus Amebocyte Lysate (LAL) Test

## USP <645> Conductivity USP:

Effluent is tested during the manufacturing process and shown to meet the requirements for USP Sterile Water for Injection for conductivity.

## USP <87> / ISO 10993-5 Cytotoxicity:

Extract from this product is non-Cytotoxic.

## Hemolysis ASTM F756-17:

Extract from this product is non-Hemolytic.

## Human and Veterinarian Use:

The product is safe for Human and Veterinarian use. CGMP CFR part 210 & 211, additional requirements of 21 CFR part 600 and 21 CFR part 680 are applicable to the aseptic manufacturing process.

## Animal-Derived Components & TSE/BSE Risk:

No animal-derived material is intentionally added or used during the manufacture of this product.

## Shelf Life:

The JKP capsules have a shelf life of 3 years from the date of sterilization.

Ethylene Oxide (ETO) Sterilized product packaging provides adequate protection to maintain a sterile barrier throughout the product's distribution, handling, and 3-year shelf life.



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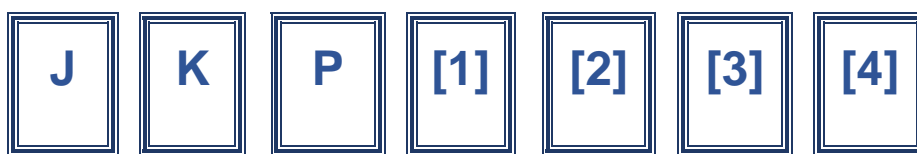


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## JKP- Series PES Junior Capsules (Pharmaceutical Grade)

### Ordering Guide



[1]	[2] Inlet and [3] Outlet	[4]
Micron Rating [Pre-Filter/Final Filter]	Inlet and Outlet Connection	Sterilization
<ul style="list-style-type: none"><li>DS065S020 : Highly Asymmetric 0.65/0.2 µm</li></ul> Note: All final membranes are sterilizing grade.	<ul style="list-style-type: none"><li>2H : 1/4" Hose Barbs</li></ul>	-ETO  Ethylene Oxide Sterilization

### Example:

**JKPDS065S0202H2H-ETO**

PureFlo® JKP Series Junior Capsule, Dual Layer Highly Asymmetric Pre-Filter PES 0.65µm / 0.2µm PES membrane (Sterilizing Grade), Filtration Area 260 cm<sup>2</sup>, 1/4" Hose Barb Inlet and 1/4" Hose Barb Outlet, ETO Sterilized (Factory Sterilized)

Part Number

Description



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## **Special Configuration:**

### **Layer Option:**

- Dual Layer

### **Micron Rating Option:**

- 0.04 Micron
- 0.1 Micron
- 0.2 Micron
- 0.45 Micron
- 0.65 Micron
- 0.8 Micron
- 1.2 Micron

### **Inlet Fitting Option:**

- 1H : 1/8" Hose Barb
- 1Q : 1/8" Male Quick Coupling with Metal Latch
- 2H : 1/4" Hose Barbs
- 2H-FB : 1/4" Hose barbs with Filling Bell
- 2Q : 1/4" Male Quick Coupling for Metal Latch
- 2N : 1/4" MNPT
- 3H : 3/8" Hose Barbs
- LF : Luer Loc Female
- MT : 1/2" Tri clamps

### **Outlet Fitting Option:**

- 1H : 1/8" Hose Barb
- 1Q : 1/8" Male Quick Coupling with Metal Latch
- 2H : 1/4" Hose Barbs
- 2H-FB : 1/4" Hose barbs with Filling Bell
- 2Q : 1/4" Male Quick Coupling for Metal Latch
- 2N : 1/4" MNPT
- 3H : 3/8" Hose Barbs
- LM : Luer Loc Male
- MT : 1/2" Tri clamps



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